REMARKS/ARGUMENTS

Upon entry of this amendment, claims 1-7 and 14-22 are pending in this application and are presented for examination. Claims 8-13 have been canceled without prejudice. Claim 22 has been withdrawn from consideration by the Examiner as being directed to a non-elected invention. Claims 15, 16, 18, and 19 have been amended. No new matter has been introduced with the foregoing amendments. Reconsideration is respectfully requested.

I. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 15, 16, and 18-21 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. To the extent the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection.

The Examiner alleges that claims 15 and 16 are vague and indefinite since they recite "microbial antigens other than OmpC associated with Crohn's disease." In order to expedite prosecution of the present case, Applicants have amended the claims to delete this term and replace it with "additional microbial antigens."

The Examiner also alleges that claim 18 is vague and indefinite because it is unclear how the presence or absence of IgA anti-OmpC antibodies and ASCA can be differentially detected and independently used for diagnosing Crohn's disease. In order to expedite prosecution, Applicants have amended the claim to clarify that the presence or absence of IgA anti-OmpC antibodies is detected using one dilution of the sample while the presence or absence of ASCA is detected using another dilution. For example, the instant specification describes the detection of IgA anti-OmpC antibodies using patient sera at a 1:100 dilution (*see,* Example II on pages 32-33) and the detection of ASCA using patient sera at a 1:80 dilution (*see,* Example III, Section C on page 36). As a result, Applicants believe that it is clear that different aliquots of the sample are independently used to provide a diagnosis of Crohn's disease.

In addition, the Examiner alleges that claim 19 is vague and indefinite for the same reason as claim 18. In response, Applicants have amended claim 19 to clarify that IgA anti-OmpC antibodies and ASCA are detected using independent enzyme-linked immunosorbent

assays. Support for the amendment is found, for example, in Examples II and III as described above.

In view of the above amendments to the claims, Applicants respectfully request that the Examiner withdraw all the 35 U.S.C. § 112, second paragraph rejections.

II. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 1-7 and 14-21 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to provide enablement for using solely IgA anti-OmpC antibody as a diagnostic marker for diagnosing the presence of Crohn's disease. To the extent the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection.

Applicants submit herewith a Declaration of Ms. Esther Oh under 37 C.F.R. § 1.132 ("the Declaration"). In the Declaration, Ms. Oh describes an analysis she performed to assess the ability of anti-OmpC antibodies to diagnose Crohn's disease without the use of any additional markers. Ms. Oh explains that the clinical performance of anti-OmpC antibodies in diagnosing Crohn's disease was compared to that of ASCA (*i.e.,* ASCA-A or ASCA-G), an established marker for Crohn's disease, in order to evaluate whether anti-OmpC antibodies can also be used as a sole diagnostic marker for Crohn's disease.

According to Ms. Oh, the clinical performance of anti-OmpC antibodies is comparable to that of ASCA-A or ASCA-G in diagnosing Crohn's disease (*see,* table in paragraph 7 of the Declaration). In fact, Ms. Oh declares that clinical parameters such as sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy are similar or identical for all three markers. Additionally, Ms. Oh states that the similarity in the values for the area under the Receiver Operator Characteristic (ROC) curve shows that all three markers possess comparable discriminatory power in differentiating between Crohn's disease and controls. Based on the foregoing, Ms. Oh concludes that since the use of either ASCA-A or ASCA-G alone is known in the art to be highly specific for diagnosing Crohn's disease, the striking similarity in the ability of anti-OmpC antibodies and ASCA-A or ASCA-G to diagnose Crohn's disease indicates that anti-OmpC antibodies can also be used as a sole diagnostic marker for Crohn's disease. As a result, Applicants believe that the objective

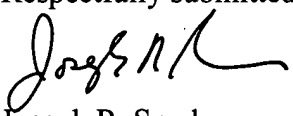
evidence presented in the Declaration provides enablement for using solely IgA anti-OmpC antibody as a diagnostic marker for diagnosing the presence of Crohn's disease. Thus, Applicants respectfully request that the Examiner withdraw the 35 U.S.C. § 112, first paragraph rejection.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,



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Attachments
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